IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

TOSHIKO OKUDA, Plaintiff, v. WYETH, et al., Defendants.	ORDER ON DEFDENDANTS' MOTIONS IN LIMINE Case No. 1:04-cv-80 DN District Judge David Nuffer

After careful review of the memoranda and other materials submitted by the parties, the Court rules on Defendants' motions in limine as follows:

IT IS HEREBY ORDERED that Defendants' motion in limine no. 1 (docket no. 178) to exclude argument regarding punitive damages is GRANTED. Under Utah Code Ann. §78B-8-203:

> (1) Punitive damages may not be awarded if a drug causing the claimant's harm:
>
> > (a) received premarket approval or licensure by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301 et seq. or the Public Health Service Act, 42 U.S.C. Section 201 et seq. . . .

The requirements of this statute are disjunctive, so that subparagraph (1)(b), applicable to over-the-counter medications, is not applicable.[1] The statute makes no exception to its application based on the relative time of use and approval or based on off-label use or concurrent use with other approved drugs. The issue of preemption does not arise because Plaintiff has produced no evidence that Defendants withheld or misrepresented information Defendants were required to submit to the FDA. In light of this ruling, Plaintiff shall not characterize Defendants' actions as

[1] *Compare* Ohio Rev. Code Ann. § 2307.80(C)(1); Or. Rev. Stat. Ann. § 30.927; and N.J. Stat. Ann. § 2A:58C-5.

malicious or reprehensible or argue (or imply) that the jury should punish Defendants by an award of damages.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 2 (docket no. 233) to exclude evidence and argument regarding the number of women whose breast cancers were purportedly caused by hormone therapy is DENIED. This evidence is relevant to the issue of general causation, as well as the need for further testing, the adequacy of the warnings given, and the risk/benefit analysis. Weaknesses in the studies giving rise to these numbers may be established on cross-examination or by Defendants' experts.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 3 (docket no. 235) to exclude marketing evidence on which neither Plaintiff nor her physicians relied is GRANTED. Plaintiff has thus far failed to present evidence that she or her physicians relied on specific marketing materials. They are not admissible as circumstantial evidence of the source of any belief of Plaintiff or her physicians in off-label benefits, because that connection is too speculative and the marketing evidence will confuse the jury and needlessly consume time.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 4 (docket no. 237) to exclude evidence of medical articles purportedly "ghostwritten" by professional writers acting on Wyeth's behalf is GRANTED. Plaintiff has not produced sufficient evidence that she or her prescribing physicians relied on any ghostwritten article in taking or prescribing the HRT drugs at issue or that the information in the articles is false. The fact that Wyeth was engaging in a fairly common, but little known practice, with a pejorative name would distract the jury and needlessly consume time. Plaintiff relies on the articles to show that Defendants were actively engaged in a campaign to overemphasize the benefits and downplay the breast cancer risks.

However, the overpromotion theory only comes into play if the warnings given were adequate *and* the prescribing physicians disregarded the warnings in reliance on the promotional materials.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 5 (docket no. 239) to exclude causality assessments made by clinical investigators when medical study participants report an adverse medical event in the course of the study is GRANTED IN PART AND DENIED IN PART. The causality assessments are relevant to the issue of Defendants' knowledge of the association between their HRT drugs and breast cancer. To that extent, the motion is denied. However, the evidence is not admissible to rebut the contention by Defendants' experts that it is not scientifically possible to determine the cause of breast cancer with respect to a particular patient. Similarly, the evidence may not be used to argue that Wyeth's causality assessments are similar to, or otherwise demonstrate support for, the causation analysis offered by Plaintiff's experts. The causality assessments are clearly not a scientifically reliable means to determine the cause of cancer and will not be admitted for this purpose. For this same reason, the results of any such causality assessment will not be admitted. Accordingly, except as outlined above, the motion is granted.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 6 (docket no. 241) to exclude warnings and labeling changes that post-date Plaintiff's use of hormone therapy medications is DENIED. These labels may be used to establish proximate cause on the issue of the adequacy of the warnings: that adequate study would have resulted in stronger warnings and such warnings would have changed the plaintiff's physicians' prescribing practices. Plaintiff intends to establish that her physicians would have and actually did alter their prescription practices in the face of these warnings. The new warnings and labels are not subsequent remedial measures under Fed. R. Evid. 407 because they were required by the FDA.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 7 (docket no. 243) to exclude any evidence or testimony regarding testing that could have been done to further investigate the potential link between Defendants' hormone therapy ("HT") medications and breast cancer risk is DENIED. This order is consistent with the order entered July 6, 2012 (docket no. 231). Also consistent with that order, opinion evidence purporting to set or identify an objective standard for testing that Defendants should have performed will not be permitted. A curative instruction may be appropriate to clarify the lack of an objective standard for testing.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 8 (docket no. 245) to exclude at trial evidence and argument regarding Defendants' sales representatives' who did not call on or influence Plaintiff's prescribers during the relevant time period, *i.e.*, when Plaintiff was taking Defendants' estrogen and progestin (E+P) drugs, is GRANTED.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 9 (docket no. 247) to exclude evidence of the relationship between Premarin and endometrial cancer is GRANTED IN PART AND DENIED IN PART. While it may be that, as Plaintiff claims, "[h]ormones cause hormone-receptor positive cancers by promoting the growth of existing hormone–dependent abnormalities into full-blown, clinical cancer,"[2] evidence of the relationship between Premarin and endometrial cancer has the potential for confusion and prejudice. The court is alerted to this issue, and shall ensure that Plaintiff limits presentation of and emphasis on such evidence. Plaintiff may not argue that because Premarin was linked to endometrial cancer, then E&P HT causes breast cancer, or that Defendants' response to the endometrial cancer issue in 1975 means they must have been aware of and hiding the breast cancer risk of E&P HT. Evidence of the 1975 conflict between the FDA and Wyeth over the marketing response to the Premarin-

[2] Plaintiff's Opposition to Defendants' Motion in Limine No. 9 . . . at 3, docket no. 289, filed July 16, 2012.

endometrial cancer link appears to violate Rule 404. If Defendants argue that when FDA standards are met they have no additional duties, Plaintiff may present evidence of Defendants' response to the discovery of the endometrial cancer/estrogen association and the FDA's response to Defendants.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 10 (docket no. 249) to exclude evidence and testimony regarding prescription data collected by IMS Health Inc. is DENIED. According to Defendants:

> IMS collects and analyzes pharmaceutical prescription data, then sells the results to the pharmaceutical industry, which uses the information for marketing and other business purposes. IMS purchases data on filled prescriptions (stripped of information that would identify patients) from approximately 70 percent of United States pharmacies.[3]

This information may be helpful to show that prescribers changed their prescription issuance after the WHI study results became available in 2002. However, Plaintiff has not demonstrated foundation for admission of the IMS data, so admissibility is not determined. HT use and incidence of breast cancer before and after the WHI report have been regarded as related and are thus relevant to the issue of causation.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 11 (docket no. 251) to exclude reference to and evidence of Defendants' wealth, profit margins for hormone therapy and/or alleged "profit motive" is GRANTED. Defendants' wealth has no relevance to this case, except to the extent Defendants might argue that they were financially unable to complete any necessary testing. Defendants have given no indication that they intend to do so. Defendants' motives are not central to this case.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 12 (docket no. 253) to preclude Plaintiff from making any reference to the absence of a corporate representative for

[3] Defendants' Memorandum in Support of their Motion in Limine No. 10 . . . at 2, docket no. 250, filed July 6, 2012.

Defendants at trial is DENIED. The presence or absence of a corporate representative (or a fact witness) is not evidence but is a fact of the procedure of trial. It may be argued, and counter-argument may be made.

IT IS FURTHER ORDERED that Defendants motion in limine no. 13 (docket no. 255) to exclude improper and prejudicial statements and argument is DENIED. The parties are, however, reminded that the trial order contains specific instructions regarding courtroom behavior and that:

- Opening statements are *statements* and not argument;
- Brief opening statements tend to help the jury while detailed and long opening statements by counsel who are deeply familiar with the facts of the case tend to confuse and bore the jury;
- Referring to evidence barred by orders in limine, or to information the parties are not prepared to submit as admissible evidence, is improper;
- Closing arguments must not refer to facts that are not in the record, misstate the evidence, or allude to personal knowledge or opinion;
- No statement should be made to the jury regarding objections made, sustained or overruled; and
- No statement should be made to the jury about opposing counsel's state of mind or motivation.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 14 (docket no. 257) to exclude reference to and evidence of a 1985 material safety data sheet (MSDS) addressing exposure to medroxyprogesterone acetate (MPA) is DENIED. The MSDS may be evidence that Upjohn was aware that the substance could aggravate breast cancer, a central issue in this case.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 15 (docket no. 259) to preclude any reference to letters sent to Upjohn by the FDA regarding unrelated advertisements is DENIED at this time. Without seeing the letters, and knowing the context in which they may be used, barring the letters is inappropriate.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 16 (docket no. 261) to bar any reference to the upward and downward sales trends for hormone therapy (HT) before

and after the Women's Health Initiative (WHI) report in July 2002 is DENIED. HT sales trends and incidence of breast cancer before and after the WHI report have been regarded as related and are thus relevant to the issue of causation.

IT IS FURTHER ORDERED that Defendants' motion in limine no. 17 (docket no. 263) to exclude from evidence at trial two letters — a letter from the FDA to Upjohn dated August 16, 2000, and the response from Upjohn's counsel dated November 7, 2000 is DENIED. While the motion suggests it seeks to "preclude Plaintiffs from referring directly or indirectly to any FDA letters to Upjohn regarding unrelated hormone therapy drugs," no other letters were discussed in the briefing papers.

Dated July 24, 2012.

BY THE COURT:

David Nuffer
United States District Judge